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10/542,049	07/13/2005	Sylvain Diguët	4662-49	6355

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EXAMINER
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PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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1615

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02/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/542,049	Applicant(s) DIGUET ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>13 July 2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

The Examiner thanks the Applicants for their timely reply filed on 11 January 2008, in the matter of 10/542,049.

Applicant's election of Group II, claims 21-23, in the reply filed on 11 January 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention and species, there being no allowable generic or linking claim. Applicants timely traversed the restriction (lack of unity) requirement between the product and method of making.

The remaining claims 21-23 are presented and represent all claims under consideration.

### ***Priority***

This application is the National Stage filing of International Patent Application No. PCT/EP04/02821, filed 18 March 2004, and European Application (EPO) 03007009.8, filed 27 March 2003. Examiner finds that Applicant's filing meets the priority requirements for the International Application, but not the Foreign Application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of Applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed with the European Patent Office on 27 March 2003. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

As such it is determined that the earliest effective U.S. filing date to be 18 March 2004.

### ***Information Disclosure Statement***

An Information Disclosure Statement filed 13 July 2005 is acknowledged and has been reviewed.

### ***Specification***

The abstract of the disclosure is objected to because it is directed to non-elected subject matter. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

Claim 22 is objected to because of the following informalities: lines 2-3 of the claim recites "Vitamin A in a total concentration range from 800,000 IU vitamin A/g beadlet to 1,500,000 IU **Mg** beadlet". The bolded text is construed as a potentially confusing typographical error. Examiner will consider this to read as "vitamin A/g beadlet" for purposes of examination on the merits.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the core region" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim recites a "core" and a "surface region", but no previous recitation of a "core region".

The term "surface region" in claim 21, is also indefinite because it is not clear if the term is directed to a coating or the inherent surface of a particle. The broadest reasonable interpretation of the term "surface region", for the purposes of examination herein, is that it refers to the inherent surface of a particle.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is

(a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 21 and 22 both recite the broad recitation "the surface region contains less than 10% ... of the total active ingredient content", and the claim also recites "the surface region contains less than 5% ... of the total active ingredient content" which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Scialpi (U.S. Patent 4,670,247).

The independent claim 21 is directed to a cross-linked beadlet whose core contains one or more of a fat-soluble vitamin, a carotenoid and a polyunsaturated fat wherein the surface region of the core contains less than 10% or less than 5% of the total active agent.

Such compositions are taught to be made by Scialpi. Claims 1-4 teach that the cross-linked beadlet core (e.g. particulate) is formed as a fat-soluble vitamin active particulate composition containing 20-30% of a vitamin. The core particulate composition formed, as stated earlier, inherently has a surface region to it. The teachings of Scialpi are silent to the presence of any percentage of any type of active agent on said inherent surface region. The individual

droplets are collected in a mass of starchy powder in such a manner as to maintain separation of the vitamin-active particles (col. 1, lines 51-54). Since the starch-based collecting powder is not taught to contain any of the active ingredient(s), Scialpi teaches that the surface region contains less than either 10% or 5% of the total active ingredient present on the surface region of the beadlet.

Therefore each and every one of the limitations is met by the reference.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Borenstein et al. (U.S. Patent 5,043,170).

The independent claim 21 is directed to a cross-linked beadlet whose core contains one or more of a fat-soluble vitamin, a carotenoid and a polyunsaturated fat wherein the surface region of the core contains less than 10% or less than 5% of the total active agent. The independent claim 22 is directed to the same composition, but is further limited by its definition of ranges for concentrations of Vitamins A, D, E, a carotenoid, and a polyunsaturated fat.

Such compositions are taught to be made by Borenstein et al. Claim 1 teaches poultry feed particles comprising Vitamin D<sub>3</sub>. Claims 3 and 4 further specify that the particles are in the form of beadlets. Said beadlets are also taught to be cross-linked (col. 4, lines 57-58). As with Scialpi, the beadlet composition formed by the invention of Borenstein et al., inherently has a surface region to it. Also like the teachings of Scialpi, the teachings of Borenstein are silent to the presence of any percentage of any type of active agent on said inherent surface region. Part B of Example 2 teaches blending an encapsulating agent and a plasticizer with water to make a 50% aqueous solution (col. 7, lines 63-64). The lipid phase containing the active vitamin D<sub>3</sub> is then encapsulated by the 50% aqueous solution. Since the lipid phase and not the aqueous phase

is in possession of the active vitamin D<sub>3</sub>, Borenstein teaches that the surface region contains less than either 10% or 5% of the total active ingredient present on the surface region of the beadlet. The independent claim 22 recites a limitation to the composition such that vitamin D is present in a total concentration ranging from 100,000 IU to 500,000 IU per gram of beadlet. Example 2 cites a composition for beadlets whose label cites 100,000 IU Vitamin D<sub>3</sub>/gram (col.7, lines 59-60).

Therefore each and every one of the limitations is met by the reference.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scialpi (U.S. Patent 4,670,247) in view of Remington (19<sup>th</sup> ed.) and Hamer et al. (U.S. Patent 6,413,548).



The instant independent claims 21 and 22 are both directed to cross-linked beadlet compositions, as described above. The dependent claim 23 recites the following range limitations to the ingredients of the composition of claim 22:

30-45% vitamin A

0-2% vitamin D<sub>3</sub>

5-15% 6-ethoxy-1,2-dihydro-2,2,4-trimethylquinolone (ethoxyquin)

25-35% gelatin

5-10% fructose

2-10% glycerine

0-1% edible fat

0-25% corn starch

5-10% calcium silicate

Water

Scialpi teaches such compositions in claims 1-4. However, claim 4 teaches the following specific compositional ranges:

20-30% of a vitamin

5-13% of an antioxidant

35-45% gelatin

2-20% of a reducing sugar

0-15% of a humectant

5-20% of a hydrophobic starch

Water to volume

As shown above, the limitation of 20-30% of a vitamin is taught in claim 4, which reads on the vitamin composition of the instant claim 23 since Vitamin D<sub>3</sub> may be absent from the composition. Ethoxyquin is taught as an antioxidant (col. 2, lines 35-39). Fructose is taught as a reducing sugar (col. 2, lines 25-26). Glycerin is taught as a humectant (col. 2, lines 38-39).

Scialpi teaches that a preferred collecting powder for the composition consists substantially of a starch modified to include hydrophobic groups (col. 3, lines 7-11). Remington further teaches that starches, such as corn starch, are insoluble in cold water and that even when it is boiled with about 20 times its weight of hot water it does not become a solution (page 1414), thereby exhibiting hydrophobic properties. Scialpi teaches a composition is silent to fat, which reads on the instant composition since having 0% fat is possible. Scialpi, as discussed earlier, does not expressly teach calcium silicate as part of the composition. However, silicic acid, which is a functional equivalent to calcium silicate, is taught as being added to the starch-based collecting powder (col. 2, lines 60-64) used to collect the composition into its beadlet form. Lastly, each of the Examples teaches the inclusion of distilled water in the beadlet formulations.

Hamer et al. teaches a stable encapsulant system comprising hydrophobic droplet particles further comprising vitamins, pigments and powders (claims 12, 13, and 15). The powders, which are taught between 5-50% and most preferably between 10-40%, can include corn starch or calcium silicate or both (col. 17, lines 18-35).

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to prepare a cross-linked beadlet product using a fat-soluble vitamin active agent such as Vitamin A or Vitamin D (e.g. Vitamin D<sub>3</sub>) in combination with a mixture comprised of pharmaceutically acceptable humectants, antioxidants, sugars and powders with a reasonable expectation of stably forming the bioactive agent into a "cored" particulate formulation. Such would have been obvious in the absence of evidence to the contrary because Scialpi teaches the components of the instant composition in claim 4 and specific components throughout the disclosure, as referenced above.

However, neither of the references teaches adding the active ingredients in the amounts claimed by Applicant. The amounts of specific ingredients in a composition are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve any of the desired results cited in the instant claims 22 and 23. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts would have been obvious at the time of Applicant's invention.

No claims are allowed.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

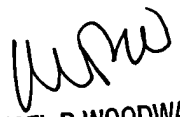
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